

§ 558.128

21 CFR Ch. I (4–1–02 Edition)

(b) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(ii) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent) carbarsone plus 10 grams per ton bacitracin from bacitracin methylene disalicylate.

(a) *Indications for use.* As an aid in the prevention of blackhead; for increased rate of weight gain.

(b) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent) carbarsone plus 4 to 45 grams per ton bacitracin from bacitracin zinc.

(a) *Indications for use.* As an aid in the prevention of blackhead, increased rate of weight gain, and improved feed efficiency.

(b) *Limitations.* Feed continuously as sole ration. Withdraw 5 days before slaughter. As sole source of organic arsenic; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter.

(2) Carbarsone (not U.S.P.) may be used in accordance with the provisions

of this section in the combinations provided as follows:

(i) Zoalene in accordance with § 558.680.

(ii) Amprolium as in § 558.55.

(iii) Bambermycins as in § 558.95.

[41 FR 10995, Mar. 15, 1976, as amended at 42 FR 18617, Apr. 8, 1977; 46 FR 46797, Sept. 22, 1981; 48 FR 2758, Jan. 21, 1983; 51 FR 7396, Mar. 3, 1986; 52 FR 2687, Jan. 26, 1987; 53 FR 20843, June 7, 1988; 57 FR 7652, Mar. 4, 1992; 61 FR 515, Jan. 8, 1996; 61 FR 18082, Apr. 24, 1996; 62 FR 61011, Nov. 14, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001]

§ 558.128 Chlortetracycline.

(a) *Approvals.* See sponsors in § 510.600(c) of this chapter for Type A medicated articles containing the following concentrations of either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride:

(1) Nos. 046573, 053389, and 066104: 50 to 100 grams per pound.

(2) No. 017519: 50 grams per pound.

(b) *Related tolerances.* See § 556.150 of this chapter.

(c) [Reserved]

(d)(1) It is used in feeds as follows:

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/t		1. Chickens; increased rate of weight gain and improved feed efficiency.	Do not feed to chickens producing eggs for human consumption.	046573.  066104, 017519, 046573, 053389.
		2. Growing turkeys; increased rate of weight gain and improved feed efficiency.	Do not feed to turkeys producing eggs for human consumption.	066104, 017519, 046573, 053389.
		3. Growing swine; increased rate of weight gain and improved feed efficiency.		Do.
(ii) 20 to 50 g/t		Growing sheep; increased rate of weight gain and improved feed efficiency.		066104, 046573, 053389.
(iii) 50 to 100 g/t		Swine; reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group <i>E. Streptococci</i> susceptible to chlortetracycline.		066104, 017519, 046573, 053389.
(iv) 100 to 200 g/t		Chickens; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	1. Feed continuously for 7 to 14 d.	046573.

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(v) 200 g/t		Turkeys; control of infectious synovitis caused by <i>M. synoviae</i> susceptible to chlortetracycline.	2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	066104, 017519, 046573, 053389.
(vi) 200 to 400 g/t		1. Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 d.	066104, 017519, 046573, 053389.
		2. Ducks; control and treatment of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.	2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	066104, 017519, 046573, 053389.
			Feed in complete ration to provide from 8 to 28 milligrams per pound of body weight per day depending upon age and severity of disease, for not more than 21 d. Do not feed to ducks producing eggs for human consumption.	063238.
(vii) 400 g/t		1. Turkeys; control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	066104, 017519, 046573, 053389.
		2. Turkey poults not over 4 weeks of age; reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.		Do.
		3. Breeding swine; control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlortetracycline.	Feed continuously for not more than 14 d.	Do.
(viii) 500 g/t		Chickens; reduction of mortality due to <i>E. coli</i> infections susceptible to chlortetracycline.	1. Feed for 5 d.	046573.
			2. Feed for 5 d; do not feed to chickens producing eggs for human consumption.	066104, 017519, 046573, 053389.
(ix) 10 mg/g of finished feed daily.		Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by <i>Chlamydia psittaci</i> sensitive to chlortetracycline.	Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight. <i>Warning:</i> "Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and domestic birds, other animals, and man. Contact appropriate public health and regulatory officials."	046573

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(x) 0.1 mg/lb of body weight daily.		Calves (up to 250 lb); for increased rate of weight gain and improved feed efficiency.	In milk replacers or starter feed; include on labeling the warning: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal."	066104, 017519, 046573, 053389
(xi) 0.5 mg/lb of body weight daily.		Beef cattle (over 700 lb); control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. For sponsor 046573 zero withdrawal time. For sponsor 053389 1 d withdrawal time.	Do.
(xii) 10 mg/lb of body weight		1. Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline. For sponsor 053389 1 d withdrawal time.  2. Calves (up to 250 lb); treatment of bacterial enteritis caused by <i>E. coli</i> susceptible to chlortetracycline.  3. Swine; treatment of bacterial enteritis caused by <i>E. coli</i> and <i>S. choleraesuis</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to chlortetracycline.  4. Swine; for control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline.	Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 d; in feed including milk replacers; withdraw 10 d prior to slaughter except for 24 h for sponsor 046573; zero withdrawal for sponsor 046573; include on labeling the warning: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal."  In milk replacers or starter feed; include on labeling the warning: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal."  Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 d; withdraw 5 d prior to slaughter for sponsor 012286.  Feed for not more than 14 d.	Do.       046573
(xiii) 25 mg/lb of body weight		Turkeys; control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	Do.
(xiv) 25 to 70 mg/head/day		Calves (250 to 400 lb); increased rate of weight gain and improved feed efficiency.	Include on labeling the warning: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal."	066104, 017519, 046573, 053389
(xv) 70 mg/head/day		Growing cattle (over 400 lb) increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses.	.....do	Do.

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(xvi) 80 mg/head/day		Breeding sheep; reducing the incidence of (vibriotic) abortion caused by <i>Campylobacter fetus</i> infection susceptible to chlortetracycline.		066104, 046573, 053389
(xvii) 350 mg/head/day		1. Beef cattle; control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline. 2. Beef cattle (under 700 lb); control of active infection of anaplasmosis caused by <i>A. marginale</i> susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. For sponsor 000004 zero withdrawal time. For sponsor 053389 1 d withdrawal time.  .....do	066104, 017519, 046573, 053389  Do.

(2) For sponsor 046573: it is used in free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles; such feeds are given to beef cattle and nonlactating dairy cattle to provide a daily intake of 0.5 to 2.0 milligrams of chlortetracycline per pound of body weight to aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; the use of these Type A articles to make specific free-choice feed formulations must be approved under section 512(b) of the act and be based on a demonstration of drug stability and consumption which is consistent with the effective dose; the specific free-choice feed formulations approved in this paragraph can be manufactured under section 512(m) of the act.

(3) Chlortetracycline may be used in accordance with the provisions of this section in the combinations provided as follows:

- (i) Amprolium in accordance with § 558.55.
- (ii) Amprolium plus ethopabate in accordance with § 558.58.
- (iii) Bacitracin methylene disalicylate in accordance with § 558.76.
- (iv) Clopidol in accordance with § 558.175.
- (v) Decoquinat in accordance with § 558.195.
- (vi) Hygromycin B in accordance with § 558.274.
- (vii) Monensin in accordance with § 558.355.
- (viii) Roxarsone and salinomycin in accordance with § 558.550.

(ix) Robenidine hydrochloride in accordance with § 558.515.

(x) Roxarsone in accordance with § 558.530.

(xi) Salinomycin in accordance with § 558.550.

(xii) Zoalene in accordance with § 558.680.

(xiii) Tiamulin in accordance with § 558.600.

[41 FR 10995, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.128, see the List of Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

#### § 558.140 Chlortetracycline and sulfamethazine.

(a) *Approvals.* Type A medicated articles: 35 grams of chlortetracycline per pound with 7.7 percent (35 grams) of sulfamethazine to 046573 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(c) It is used in feed for beef cattle as follows:

(1) *Amount per head per day.* Chlortetracycline, 350 milligrams plus sulfamethazine, 350 milligrams.

(2) *Indications for use.* Aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

(3) *Limitations.* Feed for 28 days; withdraw 7 days prior to slaughter.

[61 FR 35954, July 9, 1996, as amended at 64 FR 15684, Apr. 1, 1999; 66 FR 46706, Sept. 7, 2001]